

REMARKS

Claims 1-14 are listed as pending in the application. Claim 4 has been withdrawn from consideration. Claims 1-3 and 5-14 have been both objected to and rejected.

Reconsideration and withdrawal of both the objection to, and rejection of, claims 1-3 and 5-14 are requested.

DISCUSSION

Objection to Claims 1-3 and 5-14

The Examiner objected to claims 1-3 and 5-14 for incorporating the allegedly unclear antimuscarinic agent dosing limitation "and when needed."

In response thereto, Applicants have amended claim 1 to cancel therefrom the word "and" from the phrase "and when needed" as suggested by the Examiner.

Reconsideration and withdrawal of the objection to claims 1-3 and 5-14 are requested.

Objection to Claims 6 and 10-14

The Examiner objected to claims 6 and 10-14 for being improperly dependent.

In response thereto, Applicants have amended the subject claims to recite proper dependence.

Reconsideration and withdrawal of the objection to claims 6 and 10-14 are requested.

Rejection of Claim 2 Under 35 U.S.C. §112

The Examiner rejected claim 2 under 35 U.S.C. §112, second paragraph, for use of the allegedly indefinite phrase "related compounds" as applied to the compound tolterodine.

In response thereto, and without assent as to the propriety of the basis for the rejection of claim 2, Applicants have amended the subject claim to further define the scope of tolterodine "related compounds" as "a racemate to tolterodine, the corresponding (S)-enantiomer to tolterodine, the 5-hydroxymethyl metabolite of said (S)-enantiomer to tolterodine, fesoterodine, or a pharmaceutically acceptable salt of said racemate, (S)-enantiomer, 5-hydroxymethyl metabolite, or fesoterodine. Antecedent basis for such amendment is found on page 2, lines 24-36 of the instant description.

Reconsideration and withdrawal of the rejection of claim 2 are requested.

Rejections of Claims 1-3 and 5-14 Under 35 U.S.C. §102

The Examiner rejected claims 1-3 and 5-14 under 35 U.S.C. §102 in view of the following references:

- (1) Nilvebrant, *et al.*, (U.S. Pat. No. 6,630,162; '162 hereinafter) which discloses, *inter alia*, a clinical trial in which tolterodine was administered as a controlled-release formulation in s.i.d. and b.i.d. dosing regimens;
- (2) Gren, *et al.*, (WO 00/27364 and U.S. Pat. No. 6,911,217; '27364 and '217, respectively, hereinafter) which teach methods of preparing controlled-release formulations of tolterodine for use in treating overactive bladder, which is defined therein as a dysfunction giving rise to "urinary frequency, urgency and/or urge incontinence;"

- (3) Nilvebrant, et al., (WO 00/12069; '12069 hereinafter) which discloses, *inter alia*, a clinical trial in which tolterodine was administered as a controlled-release formulation in s.i.d. and b.i.d. dosing regimens; and
- (4) Kreilgard, et al., (U.S. Pat. No. 6,770,295; '295 hereinafter) which describes, *inter alia*, a clinical trial in which tolterodine was administered as a controlled-release formulation in s.i.d. and b.i.d. dosing regimens.

In response thereto, Applicants note that the instant methods are directed to the use of tolterodine, or a related compound, for treating unstable or overactive urinary bladder wherein the tolterodine, or related compound, is administered only when the patient feels such administration is immediately warranted or desired. The Examiner's attention is directed to page 3, line 30, bridging to page 5, line 28, of the instant description. Specific reference is drawn to the clinical criteria disclosed on page 6, lines 5-15, of the instant description. Tolterodine, or the compound related thereto, is administered on an individual, as-needed basis, *i.e.*, only when deemed necessary by the patient to provide relief of extant symptoms of urinary urgency and/or frequency. Such a dosing regimen is known to one of ordinary skill in the art as p.r.n. (prescribe as needed) dosing.

With respect to the '162, '12069, and '295 references above, none disclose or suggest p.r.n. dosing regimens for tolterodine or related compounds. Rather, the references teach dosing regimens that must be strictly adhered to without deviation, *i.e.*, no allowance was made for individual variation in the timing of the prescribed dosing regimen such

that immediate relief of symptomatic urge was accommodated. The Examiner's attention is directed to column 8, lines 2-60 of the '162 reference; page 10, lines 1-22 of the '12069 reference; and column 5, lines 55-67, bridging to column 6, line 8, of the '295 reference, all of which teach the regimented, i.e., once-daily (s.i.d.) or twice-daily (b.i.d.), administration of tolterodine. Further, neither the '27364 nor '217 references teach anything whatsoever regarding dosing regimens of the controlled release formulations disclosed therein. For example, the Examiner's attention is directed to column 5, lines 42-46 of the '217 reference where a generalized teaching of tolterodine administration is set forth.

Reconsideration and withdrawal of the rejections of claims 1-3 and 5-14 are requested.

Rejection of Claims 5 and 6 Under 35 U.S.C. 103(a)

The Examiner rejected claims 5 and 6 under 35 U.S.C. 103(a) in view of Gren, et al., ('27364 hereinabove).

Section 103(c) of 35 U.S.C. provides that "[s]ubject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, . . . subject to an obligation of assignment to the same person."

In response thereto, Applicants note that Gren, et al., ('27364) is not a competent reference against the instant application because the subject matter of WO 2000/27364 and that of the instant application were, at the time the present

invention was made, both under an obligation of common assignment.

Statement of Common Ownership

U.S. Serial No. 9/763,281 (now U.S. Pat. No. 6,911,217) is the National Phase entry of WO 2000/27364 (Gren, et al.) and was, at the time the present invention was made, assigned to the Pharmacia Company (Pharmacia AB). The instant application, U.S. Serial No. 10/762,726, is also under obligation of common assignment to the Pharmacia Company, a wholly-owned subsidiary of Pfizer Inc.

In support thereof, Applicants refer to the Assignment in U.S. Serial No. 9/763,281, recorded at, *inter alia*, Reel 012217, Frame 0597, a copy of which is transmitted concurrently herewith for the Examiner's consideration, marked as "EXHIBIT A."

Reconsideration and withdrawal of the rejections of claims 1-3 and 5-14 are requested.

All claims under consideration are in condition for allowance. Such prompt and favorable action is respectfully solicited.

Respectfully submitted,

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